6.4 510(k) Summary of Safety and Effectiveness

Date	Monday, November 08, 2004
510(k) Number	K043138 (To be assigned)
Submitter's Name	Atos Medical AB P O Box 183 Kraftgatan 8 SE-242 22 Hörby Sweden Telephone: Int+46-415-198 00 Fax: Int+46-415-198 98 E-mail: info@atosmedical.com
Contact Person	Eddy Åberg Director of Quality & Regulatory Affairs
Trade or Proprietary Name	Provox® NID™ Voice Rehabilitation System
Common or Usual Name	Voice Prosthesis
Device Classification Name	Laryngeal prosthesis (Taub design)
Product Code	EWL

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Predicate Devices

Provox®2 Voice Prosthesis System
510(k) Number : K971244
Atos Medical AB, Sweden

Blom-Singer Low Pressure Voice Prosthesis
510(k) Number: K821568
Inhealth Technologies, USA

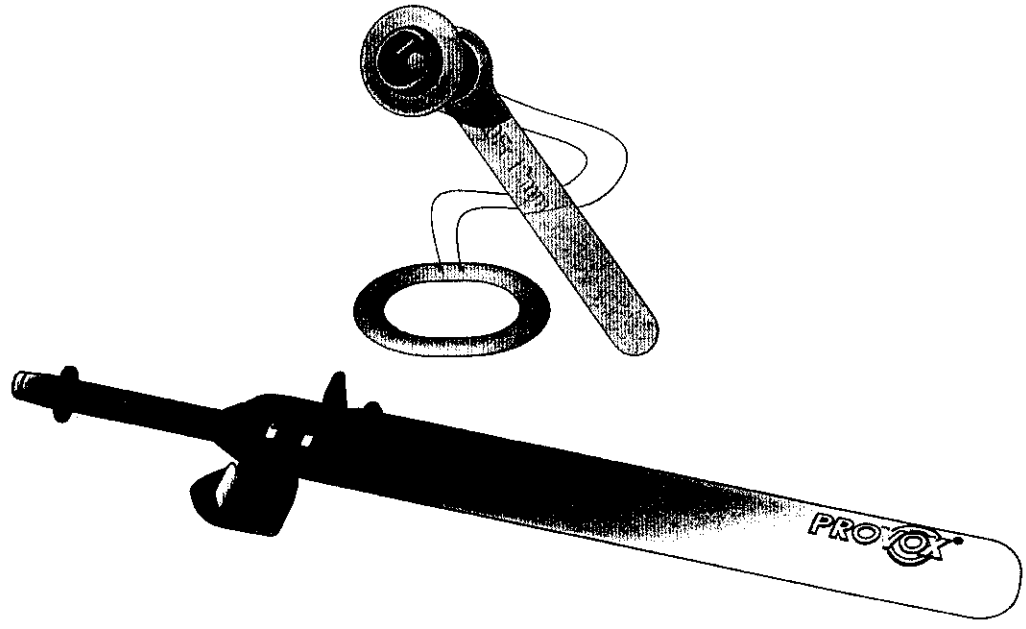
Intended Use

The Provox NID voice rehabilitation system is intended for use in prosthetic voice rehabilitation after total laryngectomy only by patients who have been trained in the use of the device and, as assessed by the clinician who prescribes the device, have demonstrated the ability to understand and consistently follow the Instructions for Use without clinician supervision.

The Provox NID is intended for single patient use.

Description of the Device

The Provox® NID™ Rehabilitation System is a non-indwelling (Standard) voice prosthesis equipped with a safety medallion, an insertion tool and some accessories.



The Provox NID voice prosthesis is available in two outer diameters (17 and 20 French) and six different lengths, (6, 8, 10, 12, 14 and 18 mm). Each prosthesis

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comes individually packed with a re-usable inserter.

The design of the device is based on the indwelling voice prostheses Provox1, Provox2 and ActiValve.

Clinical Test

Performed by Princess Alexandra Hospital, Brisbane, Australia. The Human Research Ethics Committee of the hospital approved the study.

All of the patients were using the Blom-Singer Low Pressure Voice Prosthesis prior to this study. In total, 14 patients participated in this clinical trail.

Test results support the conclusion that the actual device performance satisfies the design intent.

Technological Characteristics

The proposed device is substantially equivalent to the legally marketed predicate devices in design, intended use and materials of manufacturer.

The Provox® NID™ Rehabilitation System is provided for the same indications for use as its predicate devices, the Provox®2 Voice Prosthesis System and the Blom-Singer Low Pressure Voice Prosthesis. All three devices are designed to provide voicing after total laryngectomy. The devices are placed in a surgically created fistula between the trachea and esophagus in order to divert air through the prosthesis valve to created voicing.

Functional equivalency test have been performed on the three prostheses, which demonstrate the equivalency of the valve performance with the three designs.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

Atos Medical AB
Attn: Eddy Åberg
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Re: K043138
Trade/Device Name: Provox® NID™ Voice Rehabilitation System
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal Prosthesis (Taub design)
Regulatory Class: II
Product Code: EWL
Dated: November 8, 2004
Received: November 12, 2004

Dear Ms. Åberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6.3 Indications for Use

Applicant: Atos Medical AB, Sweden

510(k) Number: K043138 (To be assigned)

Device Name: Provox® NID™ Voice Rehabilitation System

Intended Use:

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The Provox NID is intended for single patient use.

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ **or** **Over-the-counter** ____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K043138

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